EXHIBIT A

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VIA EMAIL
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RE: *In re Valsartan Products Liability Litigation*, No. 1:19-md-02875
Core Discovery Deficiencies

Dear Counsel:

We are in receipt of your cover letters and core discovery produced in response to the Court's April 29, 2019 Order (D.E. 88) (hereafter "Court's Order") and CMO Nos. 7 and 10.

As a threshold matter, Plaintiffs need additional information from each Defendant to determine whether production of core discovery is substantially complete and in compliance with the Court's Order. Plaintiffs reserve the right to supplement these deficiencies are the review continues, and as information is provided.

Plaintiffs have conducted a comprehensive review of the almost 20,000 documents produced to date, and it is clear that Defendants differ on their understanding of what is required pursuant to the Court's Order. For example, with respect to ANDA productions, Plaintiffs have identified several ANDAs which contain the adulterated Valsartan API that were not produced, despite being the subject of FDA scrutiny in the wake of the recalls. Similarly, it appears that multiple Defendants have identified a subset of manufacturing facilities as being relevant, and have declined to produce inspection reports and associated correspondence and documents from the FDA relating to other potentially relevant manufacturing facilities operated by Defendants.

As such, in order to adequately identify the areas of disagreement on the scope of the Order, we ask that all Defendants provide the following:

- A comprehensive list of all ANDA applications submitted to the FDA by each Defendant which references or incorporated the adulterated Valsartan API. This list should specifically identify the ANDA applications which Defendants have affirmatively chosen not to produce, and Defendants' justification for not producing those ANDA files, and/or any correspondence with the FDA regarding those ANDA applications.

- A comprehensive list of all manufacturing facilities which are involved in the manufacturing of the adulterated Valsartan products, including finished dose manufacturing, and testing facilities. This list should specifically identify those facilities involved in the manufacturing of finished Valsartan product for which Defendants affirmatively chose not to produce correspondence with the FDA related to inspections (as required in ¶ 6(a)(3)(5) of the Court's discovery order), and Defendants' justification for that decision.

- A comprehensive list of all testing conducted on the Valsartan products, and the corresponding bates ranges for those results provided in Defendants' productions.

In addition to the above information, in the District of New Jersey, control is liberally construed and is based on whether the corporate relationship "establishes some legal right, authority or ability to obtain the requested documents on demand." *Camden Iron & Metal, Inc. v. Marubeni Am. Corp.*, 138 F.R.D. 438, 442 (D.N.J. 1991). Defendants who have not produced documents on behalf of all of their related entities have not indicated what efforts, if any, were made to obtain responsive documents from such other entities nor what additional relevant documents may be in those entities' possession but were not produced. Please advise what steps, if any, have been taken by you to obtain responsive documents from other entities, the status of any response, and what documents those entities may possess which were not produced.

Plaintiffs have also not received any substantive response to the meet and confer e-mail dated July 17, 2019 and subsequent e-mails on the same topic. In particular, Defendants' lack of substantive response to our request for compliant production letters, and ANDAs to be produced in eCTD format has significantly slowed and limited Plaintiffs' ability to review those ANDAs and to ensure they are complete.

Further, Defendants who have not produced documents under the Court's Order, but appear to fall within the categories of Defendants who are required to produce documents, have not acknowledged or explained their apparent violation of the Order.. Without such response, it is difficult for Plaintiffs to determine whether all Defendants who are required to produce documents have complied with the Court's Order. Please provide Defendants' position with regard to the issues raised in the July 17, 2019 meet and confer e-mails, and particularly with regard to the above two issues.

Finally, after review of the production, Plaintiffs have identified specific deficiencies with each Defendant's production. Unfortunately, due to Defendants' failure to provide all of the Court Ordered information in the cover letters on a timely basis, their continuing production of documents (for example, Plaintiffs just received a supplemental production from Mylan yesterday), and their failure to address Plaintiffs' requests for ANDAs to be provided in eCTD format, the below list is unlikely to encompass a complete list of all deficiencies that may exist in Defendants' productions. As an example, Plaintiffs have noticed that expected correspondence and supplements appear to be missing from specific ANDA productions, however, we cannot be sure whether such documents actually exist. Thus, in the interest of beginning to work cooperatively with Defendants, Plaintiffs have identified what appears to be the most glaring deficiencies as a natural starting point for conferring between the Parties, but we have additional concerns regarding non-production of expected documents.

Prinston/Zhejiang Huahi Pharmaceutical/Solco

Plaintiffs observe that Zhejiang Huahai Pharmaceutical did not directly produce core discovery documents. First, please confirm that all documents responsive to the core discovery requests in the possession, custody, or control of Zhejiang Huahai Pharmaceutical have been produced through Prinston and Solco. Second, if Zhejiang Huahai Pharmaceutical documents were produced through Prinston and Solco, explain why they were produced together and why there is no separate Bates label for Zhejiang Huahai Pharmaceutical documents.

Beyond this issue, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 5 of the Court's Order by identifying the specific bates ranges for each category of document in its cover letter enclosing production.** Prinston's July 1, 2019 and July 20, 2019, production letters failed to include this information.

2. **Failure to comply with ¶ 6(a)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence**). Prinston failed to produce EIRs or Form 483s for many inspections conducted of its Linhai facilities, including inspections conducted in March 2007, November 2016, and August 2018.

3. **Failure to comply with ¶ 6(a)(3)(4) of the Court's Order (supplements to the manufacturing process from 2010 to present).** Prinston's production of the annual reports for their Valsartan products only begins in 2015. Please confirm that no earlier supplements exist for all the products.

Mylan

1. **Failure to comply with ¶ 6(a)(1) of the Court's Order (ANDA file production).** Mylan failed produce the ANDA file for its Amlodipine Valsartan HCTZ product (ANDA 20473), which ultimately did not receive FDA approval. The FDA's denial of this ANDA application was a result of contamination issues and is highly relevant to the claims at issue. *See* MYLAN-MDL2875-00029879.

2. **Failure to comply with ¶ 6(a)(3)(2) of the Court's Order (testing documents).** Production included testing results based on API batch numbers but there is no corresponding document identifying results based on US NDC code/lot number. To the extent this document was produced, please identify the Bates range. If not, please confirm that no such document exists.

3. **Failure to comply with ¶ 6(a)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Mylan failed to provide "all FDA Form 483s, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue." Specifically, Mylan failed to produce the following:

    a. Inspection reports, Form 483s, warning letters, EIRs, or correspondence between Mylan and the FDA related to inspections of the Nashik, India facility (e.g., September 2016 inspection which resulted in a Warning letter; April 2017 Warning letter; November 2018 inspection which resulted in a Warning letter).

    b. Inspection reports, Form 483s, warning letters, EIRs, or correspondence between Mylan and the FDA related to inspections of the Morgantown, WV facility (e.g., inspections that occurred in November 2016, March and April 2018).

    Both of these facilities played critical roles in the manufacturing of Mylan's adulterated Valsartan products and are referenced throughout the ANDA submissions to the FDA for Mylan's various Valsartan products and are relevant to the claims and issues in this litigation.

4. **Failure to comply with ¶ 6(a)(3)(6) of the Court's Order (list of customers).** Mylan failed to provide customer lists that identified customers who received its products from the time its Valsartan HCTZ product entered the market in 2012. The list of customers produced by Mylan only listed wholesale distributors who, at the time of the valsartan recall, had adulterated product in their stores.

5. **ESI Deficiencies.** Documents produced with .xsl; .xml; .joboptions; .dtd; and .txt format appear to display as coding or a series of letters and numbers. Please confirm that these filetypes were produced correctly and in accordance with the ESI protocol.

Hetero

Hetero's production correspondence indicated that it was "working with Hetero USA to identify and produce further documents in its possession concerning communications with the FDA relating to the ARB recall" and that additional documents would be produced on a rolling basis. Plaintiffs never received a subsequent production. Therefore, please confirm that there are no further documents in Hetero USA's possession, custody, or control responsive to this request. To the extent Hetero USA is not in possession, custody, or control of these documents, the Court ordered you to disclose the identification of the location of documents. For documents which were not produced, you have failed to satisfy this obligation.

Beyond these issues, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Hetero USA failed to provide "all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue." Plaintiffs are aware of several investigations by the FDA of Hetero's facilities, including inspections on or around December 2016 and February 2018. One of these investigations resulted in a warning letter sent by the FDA on August 15, 2017. Hetero has produced none of these documents. To the extent Hetero USA is not in possession, custody, or control of these documents, it failed to identify where the documents are located or what steps, if any, have been taken by you to obtain responsive documents from other entities, and the status of any response.

2. **Failure to comply with ¶ 6(b)(3)(2) of the Court's Order (testing documents).** Hetero's Production included testing results based on API batch numbers but there is no corresponding document identifying results based on US NDC code/lot number. In addition, there are no documents identifying whether and to what extent API batches were combined to create pills distributed in the US. To the extent these documents were produced, please identify the Bates ranges. If not, please confirm that no such documents exist.

3. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers).** Hetero USA failed to provide "a list of all United States customers from 2010 to present." To the extent Hetero USA is not in possession, custody, or control of these documents, it failed to identify where the documents are located or what steps, if any, have been taken by you to obtain responsive documents from other entities, and the status of any response.

4. **ESI Deficiencies**,

   a. At least some PDFs appear to have been corrupted during Hetero USA's ingest process (e.g., HETERO_USA000027873 is supposed to be a cover letter, however the text is wonky and mostly unreadable. Document date is listed as 6/17/2019, which is a common date for many documents and suggest it is an ingest date rather than original document date. And given the existence of a file path, this should have been pulled from electronically stored eCTD files rather than scanned).

   b. At least 30 documents contain a document date of 12/31/9999. This is likely also an ingest error as these are clearly electronic documents. (e.g., HETERO_USA000010670).

   c. Certain critical documents have been provided as converted PDFs rather than original native format. In particular, the Index files for the eCTD submissions, which are natively in XML and viewable as text, were converted to PDF and apparently OCRed. Even though the OCR is mostly accurate, transcription errors from the OCR process, although rare, makes recreating the XML index (for viewing in an eCTD viewer) impossible without significant manual review. Related to the above, only 37 of the 38 submissions contain an index file. The submission with the folder identifier of 0008 has neither the index or associated index md5 file.

Aurobindo

The Court ordered Finished Product/Dose Manufacturers to produce (1) the ANDA file and (2) Communications with the FDA, and (3) "to the extent not produced by another responding defendant, the discovery listed in paragraph 6(a)" and (4) the location of documents if another responding defendant has possession, custody, or control of any of the listed documents. (emphasis added). Aurobindo's production cover letter indicated that the documents responsive to Paragraph 6(a) are located at Auro Limited in India, which has not yet been served.

However, as discussed in general above, in the District of New Jersey, *control* is liberally construed and is based on whether the corporate relationship "establishes some legal right, authority ***or ability*** to obtain the requested documents on demand." *Camden Iron & Metal, Inc. v. Marubeni Am. Corp.*, 138 F.R.D. 438, 442 (D.N.J. 1991) (emphasis added). There is no indication in your cover letter that any attempt to obtain documents from Auro Limited in India that are responsive to Paragraph 6(a) was made. Please advise what steps, if any, have been taken by you to obtain responsive documents from Auro Limited in India, and the status of any response.

Beyond these issues, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 6(b)(3)(1) of the Court's Order (communications regarding the recall).** The entire recall letter to the FDA, including all attachments, has not been produced in its entirety. Instead Aurobindo has produced portions of the recall letter. Please produce the letter, with all attachments, as a cohesive whole in its entirety.

2. **Failure to comply with ¶ 6(b)(3)(2) (testing documents).** Production appears to include only a single table of testing showing product that exceeds the FDA set threshold [Auro-MDL 2875-0020989]. Please identify Bates ranges for any other product testing results produced with core discovery. If in fact, no other test results were produced, please confirm that all testing results in the possession, custody, or control of Aurobindo have been produced.

3. **Failure to comply with ¶ 6(b)(3)(3) (communications regarding the efforts to contain, remove or detect contamination).** There appear to be a large number of communications with the FDA missing from the production. Please confirm that you have produced all such communications that are within your possession, custody, *or control*. To the extent you claim that these documents are solely in the possession of a different entity, please provide an explanation of what you have done, if anything, to obtain copies of these documents. This is particularly troublesome as some of the e-mails that were produced where the text of the e-mail provides a reasonable belief that a response would have been generated, but are missing responses. *See* Auro-MDL 2875-0020640 (a January 18, 2019 e-mail from the FDA requesting the LCMS method used to test Valsartan products, yet no response to this e-mail can be located).

4. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** First, the FDA Form 483 reports that were produced have been heavily redacted. Defendants have provided no legitimate basis for redacting forms which are typically made public. Additionally, during the June 2018 inspection, the FDA found "minimally acceptable" and "documented objectionable conditions" at the facility in New Jersey. No documentation reflecting any follow-up inspection nor any communications with the FDA regarding this appear to have been produced. Either confirm no such correspondence exists, or produce it immediately. Furthermore, No cGMP reports for 2010-2019 appear to have been produced, nor have cGMP certificates for the years 2011, 2012, 2015 and 2016 been produced.

5. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers).** Aurobindo has failed to provide "a list of all United States customers from 2010 to present." It appears that Attachment 7 – Consignee List to Attachment B for the Recall of Valsartan should, at the very least, have provided a starting point for this list, yet that document also appears to be missing. Please provide Attachment 7, and, to the extent you claim you are not in possession, custody, or control of these documents, please provide and explanation for why you so contend.

Teva

Teva has withheld over 50 documents from the custodial file of Constance Truemper, Teva's regulatory compliance manager, on the basis that they are not responsive or relevant. These documents appear to be cover emails or letters, and often present in situations where the cover email has been withheld as "not-responsive" but the attachments are deemed to be responsive and produced in their entirety. The attachments to the emails that have been withheld as "not responsive" include Teva's correspondence with the FDA regarding the Valsartan recall. *See* TEVA-MDL2875-00004316. Given the fact that the supposedly "irrelevant" document often attaches dozens of highly relevant documents, Plaintiffs doubt the propriety of this relevance redaction, and demand immediate production of these cover emails.

Beyond these relevancy determination issues, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 6(b)(1) of the Court's Order (ANDA file production).** Teva did not produce documents for ANDA 090642 and ANDA 077530. Both of these ANDAs were the subject of an information request by the FDA to Teva about NDMA contamination. *See* TEVA-MDL2875-00004067 and TEVA-MDL2875-00004486). Furthermore, for the ANDA files which Teva did produce documents, Teva's production related to ANDA 91235 appears to be woefully inadequate. More specifically, Documents in the ANDA file refer to amendments and/or submissions which occurred on the following dates, for which Teva has produced no documents/supplements or submissions: Dec 30, 2008, April 3, 2009 October 2, 2009, March 12, 2010, June 16, 2010, July 30, 2010, December 30, 2010

2. **Failure to comply with 6(b)(2) of the Court's Order (testing results).** Production of product testing results appears to be incomplete. Plaintiffs have identified a single document with testing data beginning at Bates TEVA-MDL2875-00004668. Consequently, it appears as though Teva has failed to produce testing results for NDMA for multiple drugs and NDEA levels for all drugs. To that end, please identify Bates ranges for any other product testing results produced with core discovery. If no other test results were produced, please confirm that all testing results in the possession, custody, or control of Teva have been produced.

3. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Teva failed to produce any documentation whatsoever regarding inspection reports, Form 483s, EIRs, cGMP inspection reports, warning letters or responses However, Teva's ANDA submissions to the FDA list the Jerusalem Oral Solid Dose facility as the location where the manufacturing of the Valsartan products will occur. *See* TEVA-MDL2875-00003557. Teva received a warning letter for this facility in 2010,

citing cGMP deficiencies related to laboratory reporting and systems. Yet Teva failed to produce a single document regarding the inspection of this facility.

4. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers**). Teva failed to provide customer lists that identified customers who received its valsartan products from the time they first entered the market. The list of customers produced by Teva only identifies customers with non-expired product, but does not include customers who received product that had previously expired.

Torrent

The Court ordered production of responsive documents within your possession, custody *or control* responsive to the Court's Order. The Court ordered the identification of the location of documents if another responding defendant has possession, custody, or control of any of the listed documents. For documents which were not produced, you have failed to satisfy this obligation.

Beyond these issues, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 5 of the Court's Order by identifying the specific bates ranges for each category of document in its cover letter enclosing production.** Torrent did not produce a cover letter with its initial production of documents. It then produced a single cover letter with the July 19, 2019 production, which remains deficient for the reasons articulated below.

2. **Failure to comply with ¶ 6(b)(3)(1) of the Court's Order (correspondence regarding the ARB recalls).** There appear to be significant gaps in Torrent's production of its FDA Correspondence. For example, only eight (8) FDA correspondence documents have been produced for the month of October 2018, five (5) for the month of November 2018, and a mere three (3) for the month of January 2019. It is extremely hard to believe there were no more communications between Torrent and the FDA during this time period given the information which we were able to locate and are publicly available from the FDA showing numerous additional recalls[1]. After the July 2018 recall, there were various emails between Torrent and the FDA discussing follow up questions, press releases and other mitigating measures, which have been produced. It is hard to believe there are so few responsive documents from October and November 2018 and January 2019 given additional recall actions.

3. **Failure to comply with ¶ 6(b)(3)(2) of the Court's Order (testing).** Torrent's Production included only a single table of test results for all non-expired lots with API lot numbers but

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

there is no corresponding document identifying results based on US NDC code/lot number. *See* TORRENT-MDL2875-00001294. Please identify Bates ranges for any other product testing results produced with core discovery. If, in fact, no other test results were produced, please confirm that all testing results in the possession, custody, or control of Torrent have been produced.

4. **Failure to comply with ¶ 6(a)(3)(2) of the Court's Order (investigation into the cause of the alleged contamination).** Torrent has produced only *one* response to one FDA information request regarding NDMA contamination in the four Valsartan products (specifically ANDA 202377). However, Torrent has multiple other Valsartan ANDA's (including ANDA 201593, ANDA 091654, and ANDA 202728), for which it has failed to produce the FDA request or its responses.

5. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Torrent has failed to produce any form 483s related to their manufacturing facilities. By way of one known example, Sipra labs was inspected in September of 2011, and evidence indicates that the FDA issued a Form 483 to Torrent. *See*TORRENT-MDL2875-00003444). However Torrent failed to produce this form 483 in its production.

6. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers**). Torrent produced one document responsive to the Court's Core Discovery Order for Customer Lists from 2010-Present. *See* TORRENT-MDL2875-00004218. This document's metadata states that it was created on October 1, 2015 and it was then modified August 16, 2018. The Court's Core Discovery Order specifically states that Torrent must produce customer lists from 2010-Present. Please confirm that this is the definitive customer list for that entire time period.

We ask that the above identified questions be answered, and the deficiencies be corrected immediately as we will soon submit the issues remaining in dispute to the Court as required under CMO No. 10. We are available to meet and confer should you have any questions or concerns regarding this correspondence.

Very truly yours,

ADAM M. SLATER